

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**PETITION UNDER 37 C.F.R. §§1.47(b)
and 1.42**

Docket Number:
1662/460041
(formerly 11701/46007)

Application Number
10/657,737

Filing Date
September 3, 2003

Examiner
Not Yet Assigned

Art Unit
1614

Invention Title
**PHARMACEUTICALLY ACCEPTABLE
COMPOSITION COMPRISING AN AQUEOUS
SOLUTION OF PACLITAXEL AND ALBUMIN**

Inventor(s)
KADIMA et al.

Address to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited
with the United States Postal Service with sufficient postage
as first class mail in an envelope addressed to:
Mail Stop Missing Parts, Commissioner for Patents, P.O.
Box 1450, Alexandria, VA 22313-1450 on

Date: 5/19/04 Reg. No. 46,877

Signature: [Signature]

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

The above-identified application is a continuation of U.S. Patent Application Serial No. 10/293,426, filed November 12, 2002, which is a continuation of Serial No. 09/947,420, filed September 5, 2001, which is a continuation of Serial No. 09/744,827 which is a 371 of PCT/US99/17179, filed July 29, 1999, which International Application claims the benefit of provisional application Serial No. 60/094,687, filed July 30, 1998.

The International Application was filed in the name of Novopharm Biotech, Inc. as Applicant for all designated States except the United States (Exhibit A). The inventors, Tenshuk KADIMA, Howard KAPLAN and Robert C. Tuttle, were listed as the applicants for

the United States. See attached copy of first page of published PCT application (Exhibit A).

Novopharm Biotech, Inc. assigned all of its rights in the international and national applications to Human RT in January 2001 (Exhibit B). A change of Applicant was filed with the International Bureau of WIPO on January 26, 2001 along with a Power of Attorney from Human RT appointing Dr. jur. Eva Somfai as Agent for Applicant (Exhibit C).

On January 26, 2001 Dr. Somfai (Human RT's foreign patent counsel) requested Kenyon & Kenyon (Human RT's U. S. patent counsel) to enter the national phase in the United States of PCT/US99/17179. Copies of January 26, 2001 order letter and Information Sheet for New Patent Application are attached (Exhibit D).

On January 26, 2001, Dr. Eva Somfai filed with the International Bureau a Rule 92bis letter requesting the addition of inventors, Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO (Exhibit E).

On April 26, 2001 Kenyon & Kenyon sent a letter to Dr. Somfai sending copies of the application as filed, Declaration and Assignment forms for signing by the inventors three (3) originally-named inventors and a Power of Attorney form for signing by the Assignee, Human RT. Reminder letters were sent to Dr. Somfai on June 29, 2001 and August 30, 2001.

Despite many attempts, Kenyon & Kenyon was unable to contact the three inventors, as did the foreign patent counsel. On July 9, 2003, letters were sent by Kenyon & Kenyon to the three originally-named inventors by Registered Mail, Return Receipt Requested to their last known addresses as follows:

Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan
18 Hillhouse Road
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle
782 Allegheny Drive
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:.

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of **Kenyon & Kenyon, No. 11-0600**:

- 1) Basic Filing Fee of \$770.00;
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. §1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of \$1,480.00; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By *Siu K. Lo*
Siu K. Lo
Reg. No. 46,877

KENYON & KENYON
One Broadway
New York, New York 10004
Tel: (212) 425-7200
Fax: (212) 425-5288

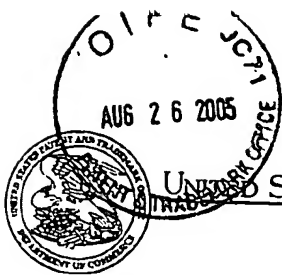
CUSTOMER NUMBER 26646

2month

0007350

1125

fig 2



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
--------------------	------------------------	-----------------------	------------------------

10/657,737

09/03/2003

Tenshuk A. Kadima

11701/46003

16621460041

CONFIRMATION NO. 8923

FORMALITIES LETTER



OC000000012904910

26646
KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

Date Mailed: 06/08/2004

NOTICE OF INCOMPLETE REPLY (NONPROVISIONAL)

Filing Date Granted

The U.S. Patent and Trademark Office has received your reply on 05/21/2004 to the Notice to File Missing Parts (Notice) mailed 11/26/2003 and it has been entered into the nonprovisional application. The reply, however, does not include the following items required in the Notice.

The period of reply remains as set forth in the Notice. You may, however, obtain EXTENSIONS OF TIME under the provisions of 37 CFR 1.136 (a) accompanied by the appropriate fee (37 CFR 1.17(a)).

A complete reply must be timely filed to prevent ABANDONMENT of the above-identified application. Replies should be mailed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

- The signature of the following inventor(s) is missing from the oath or declaration:
Lajos Hegedus, Krisztina Krempels, Krisztina Paal, Gabor Petho

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

H. Nyman
Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

P-0112

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61K 31/337, 47/48, 47/42	A1	(11) International Publication Number: WO 00/06152 (43) International Publication Date: 10 February 2000 (10.02.00)
(21) International Application Number: PCT/US99/17179 (22) International Filing Date: 29 July 1999 (29.07.99) (30) Priority Data: 60/094,687 30 July 1998 (30.07.98) US (71) Applicant (for all designated States except US): NOVOPHARM BIOTECH, INC. [CA/CA]; 30 Novopharm Court, Toronto, Ontario M1B 2K9 (CA). (72) Inventors; and (75) Inventors/Applicants (for US only): KADIMA, Tenshuk, A. [CA/CA]; 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6 (CA). KAPLAN, Howard, A. [CA/CA]; 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9 (CA). TUTTLE, Robert, C. [US/CA]; 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 (CA). (74) Agents: WU, Frank et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN		
(57) Abstract An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10 % organic solvent and has a pH of about 3.0 to about 4.8, is described. The serum albumin can be fatted or defatted, and the composition can optionally be lyophilized or optionally lyophilized and reconstituted. At least 70 % of the paclitaxel is bound to serum albumin, the ratio of paclitaxel to albumin is at least about 1:5, and the concentration of paclitaxel is at least about 25 µg/ml. Methods of making and using this composition are also provided.		

EXHIBIT B

ASSIGNMENT

We, the undersigned Assigner

Novopharm Diotech Inc.
30, Novopharm Court
Toronto, Ontario, M1B 2K9 Canada

declare to have assigned our exclusive rights related to
patent applications/patents outlined below on

HUMAN RT.
Táncsics M.u.02.
M-2100 Gódsziló, Hungary

We also agree that this assignment be entered in the
register of all international or national patent
authorities.

Data of the patent application:

Number: PCT/US00/17179
Title: "Pharmaceutically Acceptable Composition
Containing an Aqueous Solution of Paclitaxel
and Albumin"
Priority: MS 60/004607 30. July 1998

For the Assigner:

Date:
Toronto, January 2001

For the Assignee:

Date:
Gódsziló, January 2001

Signed by:



Capacity: MICHAEL A BYRNE
CHIEF FINANCIAL OFFICER

Signed by:

Lajos Hegedus

Capacity: Lajos Hegedus
General manager

P-0:12

HUMAN
SERUM PRODUCTION AND
MEDICINE MANUFACTURING
COMPANY LIMITED BY SHARES
Táncsics M. u. 02.
Gódsziló, Hungary
2100

SOMFAI & PARTNERS

H-1137 Budapest, Pozsonyi út 38

Hungary

tel: (361)3495-298

Fax: (361)3502-623

- X Special Delivery
O Air mail O Registered
O Express

X Also by fax: 1 page(s) + 1

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

Please quote on all
correspondence!

EXHIBIT C

INTERNATIONAL BUREAU OF WIPO

34, chemin des Colombettes

1211 Geneva 20

SWITZERLAND

URGENT!

Budapest, 26. January 2001

F235,236/01sé

Re:	Registration of Assignment of Application	
PCT Application:	PCT/US99/17179	29. 07. 1999
PCT Publication:	WO 00/06152	10. 02. 2000
Priority:	30. 07. 1998	US 60/094687

1. The patent application in caption and all rights related thereto were assigned from the original PCT applicant Novopharm Biotech Inc., 30. Novopharm Court, Toronto, Ontario M1B 2K9, Canada.

2. Data of the present applicant and the signatory:

Assignee:

HUMAN Rt.
Táncsis út 82.
H-2100 Gödöllő,
Hungary

Signatory:

Lajos HEGEDÚS
managing director

3. Please register the above change according to PCT Rule 92/*bis* at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.

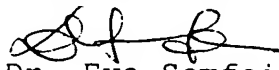
4. Please find enclosed the

- Power of attorney signed by the new applicant appointing me to represent this application.

1 page *

Thank you for your co-operation.

Respectfully



Dr. Eva Somfai
patent attorney

Enclosure:

** Fax and Mail: New Power of Attorney

Fax and Mail: Assignment Deed (follows on receipt)

P-0112

1/1

MEGHATA MAZÁS

POWER

Alulírott

The undersigned

HUMAN RT;
Gödöllő, Hungary

HUMAN RT;
Gödöllő, Hungary

ezennel meghatalmazzuk(zom) a
SOMFAI és TÁRSAI
Iparjogi Kft-t

hereby appoint(s)
SOMFAI and PARTNERS
Industrial Rights Co. Ltd.

Szabadalmi ügyvivő:
Dr jur. Somfai Éva
vegyészmémők

Patent Attorney:
Dr jur. Eva Somfai
eng. chem.
concerning
Patent and/or Application entitled

hogy az
US 60/094687
PCT/US99/17179
-ra alapított,

Pharmaceutically Acceptable Composition
Comprising an Aqueous Solution of Paclitaxel
and Albumin

Pharmaceutically Acceptable Composition
Comprising an Aqueous Solution of
Paclitaxel and Albumin

című szabadalom és/vagy bejelentés

Nº
based on
US 60/094687
PCT/US99/17179

ügyben az illetékes hatóságok, bíróságok
és hivatalok előtt teljes jogkörrel
képviseljen.

with full power of substitution and
representation before the competent
authorities, courts or offices.

Kelt/Date:

Név (Cég)/ Name (Firm):

HUMAN RT.

Cím/Address:

Táncsics M.u.82.

H-2100 Gödöllő, Hungary

Aláírás(ok)/ Signature(s)::

L. Hegedűs
Managing Director



Name and capacity of signatories

(no legalization is required)

P-0112

SOMFAI & PARTNERS

Industrial Rights Co.Ltd.

H-1137 Budapest

Hungary

11701 - 46001
RT

EXHIBIT D

Tel:(361)3495-298

Fax:(361)3502-623

X Special Delivery

o Air mail o Registered

o Express

X Also by fax: 3+6 page(s)

Nº: 00 1 212 425 5288

Your letter: -

URGENT!
IMPORTANT!

Law Office Kenyon & Kenyon
One Broadway
NEW YORK N.Y. 10004-1050
U.S.A.
X

Budapest, 26. January 2001

F231, 232/01kj

Attention of Mr. Steven J. Lee! and/or
Mr. Patrick Bird!

PRIVILEGED AND CONFIDENTIAL!

Dear Colleagues,

Re: New Patent Application in US of
HUMAN RT "NOVBIO" based on US 60/094687
PCT/US99/17179
My ref: P-0112 US Please quote!
Your ref: -
NATIONAL APPLICATION TO BE FILED in US

Please

- ☐ File a new patent application in Canada
☒ Enter the national phase of the PCT application in caption.

To be filed: On/before **30. January 2001**

- ☐ 12 months priority
☐ 20 months PCT
☒ **30 months PCT date.**

If it is possible to file within 31 months in your country please file timely before the due date.

Documents:	Now enclosed	Follows	Please inform	Remarks
Information sheet	X 2 pages			fax
PCT Publication cover	X 1 page			fax
Specification to be filed	see PCT publ			o 125 pages
Claims to be filed	see PCT publ			o 4 pages

Figures to be filed	see PCT publ			o 28 pages
Abstract	see PCT publ			o 1 page
Power			X	
Inventors decl.			X	
Transfer of rights			X	
Data of newly added inventors	X 1 page			o o
Priority document			X	
PCT Search Report				o
PCT Publication				o
Change of representation and owner filed at WIPO	X 1 page			
Completion of inventor's list filed at WIPO	X 2 pages			
Acceptance by WIPO			X	

- o is already in your file (5934/2)
- o o If you consider it would be better not to file this please
 - ☐ call me before filing any time between 9 and 19 our time
 - ☒ add the names when appropriate.

Please indicate by return fax what else you need. The outstanding documents will follow always with a copy of this letter.

We ask you to send the **filled-in Powers** and all other documents you need in the form **ready for signature**. Empty formulars will not be signed.

- ☒ The priority document was filed in English by the inventors Kadima Tenshuk, Kaplan Howard, Tuttle Robert C.
- ☒ The PCT application was filed by the assignor Novopharm Biotech, CA the prosecution was in English and the application was recently assigned. When writing this order letter the WIPO-registration of both the Assignment and completion of the list of inventors is still pending.

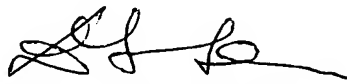
We await your debit notes in duplicate clearly indicating where and how you wish us to settle the same.

Please do not abandon this application if not expressedly instructed to do so.

Please confirm receipt both of the faxed and the mail version of this order letter as well as the documents by fax.

Thanking you for your immediate attention and looking forward to have a good co-operation.

Sincerely yours



Dr. Eva Somfai
chem. ing. patent attorney

Enclosure:

Fax:	6 page(s)
Air mail:	- page(s)
Spec. delivery	6 page(s)

INFORMATION SHEET FOR NEW PATENT APPLICATION

TITLE: Pharmaceutically Acceptable Composition
 Comprising an Aqueous Solution of
 Paclitaxel and Albumin

APPLICANT: HUMAN RT
 Táncsics M.u.82.
 H-2100 Gödöllő, Hungary

PRIORITY: 30.07.1998 US 60/094687

PCT APPLICATION: PCT/US99/17179 29.07.1999

PCT PUBLICATION: WO 00/06152 10.02.2000

INVENTOR(S): Kadima, Tenshuk
 Kaplan, Howard
 Tuttle, Robert C.
 Dr. Hegedűs, Lajos
 Dr. Krempels, Krisztina
 Dr. Paál, Krisztina
 Dr. Pethő, Gábor

TO BE
ADDED
WHEN
APPROPRIATE

To be filed: On/before **30. January 2001**

- ☐ 12 months priority
- ☐ 20 months PCT
- ☒ 30 months PCT date.

If it is possible to file within 31 months in your country please file timely before the due date.

ASSIGNMENTS:

- ☒ The priority application was filed by:
Inventors Kadima, Kaplan, Tuttle (CA)
all of Novopharm Biotech, CA.
- ☒ The PCT application was filed by:
Novopharm Biotech, CA, ~~except~~ in the US where it
was filed by inventors Kadima, Kaplan, Tuttle.
- ☒ The application was assigned on HUMAN RT., HU
registration of the change was requested in the
international phase on 26.01.2001

- ☒ The national application has to be filed in the name of HUMAN RT., HU alone.
The assignment documents will follow as soon as available.
- ☒ Because important subject matter of the claimed invention was based on the invention of the four Hungarian inventors now appearing in the list of inventors - registration of completion of the inventor's list was requested on 26.01.2001 at the WIPO.

EXHIBITE

X Special Delivery
O Air mail O Registered
O Express

X Also by fax: 1 page(s)
Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

URGENT! F237,238/01sé

INTERNATIONAL BUREAU OF WIPO
34. chemin des Colombettes
1211 Geneva 20
SWITZERLAND

Budapest, 26. January 2001

Re: **Registration of Change in Person of Inventors**
PCT Application: PCT/US99/17179 29. 07. 1999
Priority: 30. 07. 1998 US 60/094687

1. Reverting to my letter earlier this day I hereby ask to register the following further change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
2. Because important subject matter of the claimed invention was based on the invention of authors whose names did not appear in the list of inventors as originally filed, the Applicant completed the list of inventors by adding of the following persons:

- i) DR. HEGEDŰS, Lajos; chemical engeneer;
Hungarian citizen;
Eötvös út 47
H-1121, Budapest, Hungary
- ii) DR. KREMPELS, Krisztina; physician; Hungarian
citizen; Ady E. út 204
H-1188 Budapest, Hungary
- iii) DR. PAÁL, Krisztina; chemist, Hungarian citizen;
Felsőzöldmáli út 80
H-1025 Budapest, Hungary
- iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen;
Kassai út 10
H-1225, Budapest, Hungary

Thank you for your co-operation and help.

Respectfully



Dr. Eva Somfai
patent attorney

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**PETITION UNDER 37 C.F.R. §§1.47(b)
and 1.42**

Docket Number:
1662/460041
(formerly 11701/46007)

Application Number
10/657,737

Filing Date
September 3, 2003

Examiner
Not Yet Assigned

Art Unit
1614

Invention Title
**PHARMACEUTICALLY ACCEPTABLE
COMPOSITION COMPRISING AN AQUEOUS
SOLUTION OF PACLITAXEL AND ALBUMIN**

Inventor(s)
KADIMA et al.

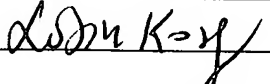
Address to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited
with the United States Postal Service with sufficient postage
as first class mail in an envelope addressed to:

Mail Stop Missing Parts, Commissioner for Patents, P.O.
Box 1450, Alexandria, VA 22313-1450 on

Date: 5/19/04 Reg. No. 46,877

Signature: 

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

The above-identified application is a continuation of U.S. Patent Application Serial No. 10/293,426, filed November 12, 2002, which is a continuation of Serial No. 09/947,420, filed September 5, 2001, which is a continuation of Serial No. 09/744,827 which is a 371 of PCT/US99/17179, filed July 29, 1999, which International Application claims the benefit of provisional application Serial No. 60/094,687, filed July 30, 1998.

The International Application was filed in the name of Novopharm Biotech, Inc. as Applicant for all designated States except the United States (Exhibit A). The inventors, Tenshuk KADIMA, Howard KAPLAN and Robert C. Tuttle, were listed as the applicants for

the United States. See attached copy of first page of published PCT application (Exhibit A).

Novopharm Biotech, Inc. assigned all of its rights in the international and national applications to Human RT in January 2001 (Exhibit B). A change of Applicant was filed with the International Bureau of WIPO on January 26, 2001 along with a Power of Attorney from Human RT appointing Dr. jur. Eva Somfai as Agent for Applicant (Exhibit C).

On January 26, 2001 Dr. Somfai (Human RT's foreign patent counsel) requested Kenyon & Kenyon (Human RT's U. S. patent counsel) to enter the national phase in the United States of PCT/US99/17179. Copies of January 26, 2001 order letter and Information Sheet for New Patent Application are attached (Exhibit D).

On January 26, 2001, Dr. Eva Somfai filed with the International Bureau a Rule 92bis letter requesting the addition of inventors, Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO (Exhibit E).

On April 26, 2001 Kenyon & Kenyon sent a letter to Dr. Somfai sending copies of the application as filed, Declaration and Assignment forms for signing by the inventors three (3) originally-named inventors and a Power of Attorney form for signing by the Assignee, Human RT. Reminder letters were sent to Dr. Somfai on June 29, 2001 and August 30, 2001.

Despite many attempts, Kenyon & Kenyon was unable to contact the three inventors, as did the foreign patent counsel. On July 9, 2003, letters were sent by Kenyon & Kenyon to the three originally-named inventors by Registered Mail, Return Receipt Requested to their last known addresses as follows:

Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan
18 Hillhouse Road
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle
782 Allegheny Drive
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of **Kenyon & Kenyon, No. 11-0600**:

- 1) Basic Filing Fee of \$770.00;
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. § 1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of **\$1,480.00**; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By *Siu K. Lo*
Siu K. Lo
Reg. No. 46,877

KENYON & KENYON
One Broadway
New York, New York 10004
Tel: (212) 425-7200
Fax: (212) 425-5288

CUSTOMER NUMBER 26646

2month

0007350

1725

Fig 11

EXHIBIT F

July 9, 2003

**VIA REGISTERED MAIL -
Return Receipt Requested**

Mr. Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba
Canada R3P 1M6

Re: U. S. Patent Application Serial No. 10/293,426
PHARMACEUTICALLY ACCEPTABLE COMPOSITION
COMPRISING AN AQUEOUS SOLUTION OF
PACLITAXEL AND ALBUMIN
Our Ref: 11701/46003

Dear Mr. Kadima:

We are contacting you on behalf of our client, Human RT.

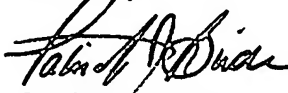
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,


Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)
Steven J. Lee, Esq. (w/o enc.)



Patrick J. Birde
Direct 212.908.6452
pbirde@kenyon.com

One Broadway
New York, NY 10004-1050
212.425.7200
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -
Return Receipt Requested**

Mr. Robert C. Tuttle
782 Allegheny Drive
Winnipeg, Manitoba
CANADA R3T 5L2

Re: U. S. Patent Application Serial No. 10/293,426
PHARMACEUTICALLY ACCEPTABLE COMPOSITION
COMPRISING AN AQUEOUS SOLUTION OF
PACLITAXEL AND ALBUMIN
Our Ref: 11701/ 46003

Dear Mr. Tuttle:

We are contacting you on behalf of our client, Human RT.

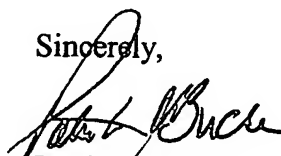
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,



Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley www.kenyon.com 608453

July 9, 2003

**VIA REGISTERED MAIL -
Return Receipt Requested**

Mr. Howard A. Kaplan
18 Hillhouse Road
Winnipeg, Manitoba
CANADA R2V 2V9

Re: U. S. Patent Application Serial No. 10/293,426
PHARMACEUTICALLY ACCEPTABLE COMPOSITION
COMPRISING AN AQUEOUS SOLUTION OF
PACLITAXEL AND ALBUMIN
Our Ref: 11701/ 46003

Dear Mr. Kaplan:

We are contacting you on behalf of our client, Human RT.

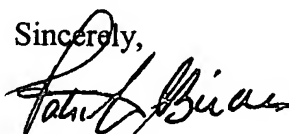
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,



Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)
Steven J. Lee, Esq. (w/o enc.)

K A D - M A

1511

EXHIBIT

G

ORK, N. Y. 10004

To: Patrick J. Bird

7th Floor

Unclassified

RECEIVED
JUL 15 1999
NEW YORK, NY 10004-1050

TURN TO SENDER
VOYA L'EXPEDITEUR

☐ Unclaimed
Non réclamé

☐ No such address
Adresse inconnue

☐ Address incomplete
Adresse incomplète

☐ Return to Post Office
Bureau de poste

☐ Refused by addressee
Refusé par le destinataire

KENYON
KENYON
Intellectual Property Law
Broadway
New York, NY 10004-1050

Mr. Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba, CANADA R3P 1M6

RETURN TO SENDER
RENOUVEAU A L'EXPEDITEUR

☒ Unclaimed
Non réclamé

☐ No such address
Adresse inconnue

☐ Address incomplete
Adresse incomplète

☐ Return to Post Office
Bureau de poste

☐ Refused by addressee
Refusé par le destinataire

United States Postal Service
REGISTERED MAIL

Label 200, July 1999

RR 605 899 896 US
(102595) 99-M-1904

CANADA POST
GRANT PARK POSTAL OUTLET
GRANT PARK
Winnipeg, MB R3P 1B0
469-1730

174369165

NEW YORK
JUL 09 03
PM
7087606
U.S. POSTAGE

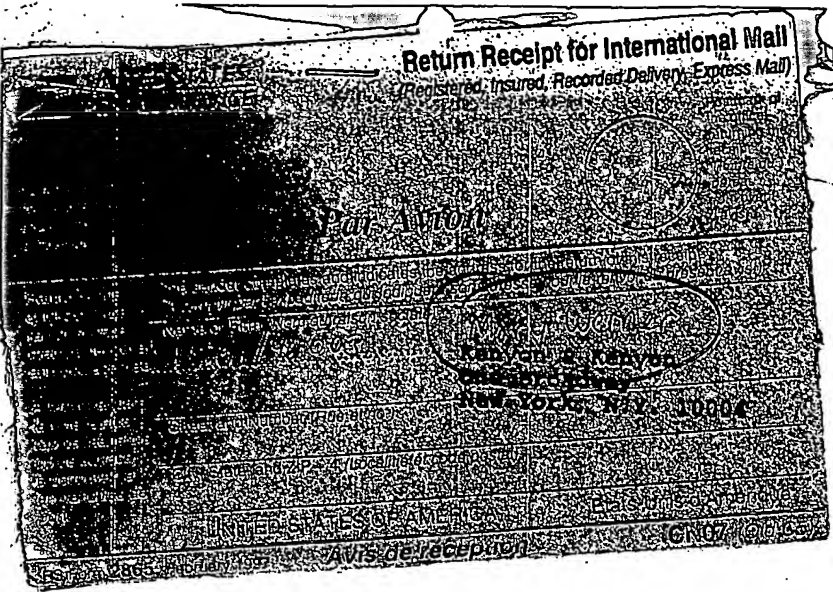


EXHIBIT H

KENYON
Intellectual Property Law

One Broadway
New York, NY 10004-1050

Mr. Robert C. Tuttle
782 Alagheny Drive
Winnipeg, Manitoba CANADA R3T 5L2

address incomplete

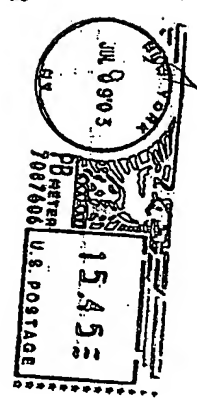
2000-07-13

2000-07-13

ADDRESS INCOMPLETE // ADRESSE INCOMPLETE
RETURN TO SENDER
RENOUVOI A L'EXPEDITEUR
NY 10004
USA

CUSTOMS
TO, ON

Quide



Werner, Mary

EXHIBIT I

From: Werner, Mary
Sent: Friday, August 01, 2003 2:03 PM
To: Butler, Timothy
Subject: RE: 11701/46001 - for Tuesday

Thanks, Tim.

-----Original Message-----

From: Butler, Timothy
Sent: Friday, August 01, 2003 2:01 PM
To: Werner, Mary
Subject: RE: 11701/46001 - for Tuesday

Mary

It turns out that they can only obtain this information for people in the US. I'm going to hold on to this and try Westlaw next week. This was the answer which I received from your Lexis representative.

-----Original Message-----

From: Werner, Mary
Sent: Thursday, July 24, 2003 6:36 PM
To: Butler, Timothy
Subject: 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

Werner, Mary

From: Butler, Timothy
Sent: Wednesday, August 06, 2003 7:22 PM
To: Werner, Mary
Subject: RE: 11701/46001 - for Tuesday

Mary
I tried again with West law . sorry no results

-----Original Message-----

From: Werner, Mary
Sent: Thursday, July 24, 2003 6:36 PM
To: Butler, Timothy
Subject: 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

PITBLADO
ATTORNEYS & SOLICITORS

EXHIBIT J

2500 - 380 Main Street
Winnipeg, Manitoba
Canada R3C 4H6

Tel. (204) 956 0560
Fax (204) 957 0227
E-mail firm@pitblado.com

Reply to:
Robert A. Watchman
Direct (204) 956 3568
watchman@pitblado.com

File No. 34052/1

VIA TELECOPIER 212-425-5288

March 22, 2004

Kenyon & Kenyon
One Broadway
New York, NY 10004-1050

Attention: **Slu K. Lo**

Dear Sir:

Re: **U.S. Patent Application Serial No. 10/293,426**
Your Reference: 1662/46003

This will acknowledge receipt of your letter dated March 11, 2004 enclosing documentation with respect to the above-noted application.

As you may recall in our telephone conversation of September 3, 2003, because of the particular wording of the inventor's declaration for the United States, the representative of Dr. Kaplan's estate cannot sign the declaration. That is, the wording requires her to declare, under threat of penalty, that she has reviewed and understands the content of the specification, including the claims, amongst other things.

We wish to emphasize that Ms. Grad does not wish to appear to be uncooperative and she is not disputing the application or your client's entitlement to the invention, it is simply that she cannot sign the declaration as worded.

In our telephone discussion, I referred to other patent applications in which the same issue arose in which the applicant proceeded on the basis that the representative "refuses" to sign the declaration, which I believe is provided for in 37 CFR 1.42.

In our September 3, 2003 telephone conversation, you indicated that you believe the rules might have provided for some variation when the documents were to be signed by a representative. However, unless there is some other wording for the declaration, the representative of Dr. Kaplan's estate will not be able to sign.

Yours very truly,

PITBLADO

for per: *Robert A. Watchman*
Robert A. Watchman
RAW:dew

ORK, N. Y. 10004

EXHIBIT

G

K # D - M A

151

Unclassified

EO, Rd 2 81 500

RECEIVED
JUL 13 1993
KENDON

7th Floor

To: Patrick J. Bide

TURN TO SENDER
VOA L'EXPEDITEUR

☐ Undelivered
☐ No such addressee
☐ Address incomplete
☐ Addressee deceased
☐ Addressee relocated
☐ No such Post Office
☐ Bureau business
☐ Refused by addressee
☐ Refused per la destinatione

KENYON
Intellectual Property Law
3 Broadway
New York, NY 10004-1050

Mr. Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba, CANADA R3P 1M6

RETURN TO SENDER
RENOU A L'EXPEDITEUR

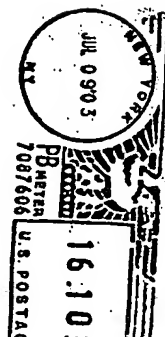
☒ Undelivered
☐ No such addressee
☐ Address incomplete
☐ Addressee deceased
☐ Addressee relocated
☐ No such Post Office
☐ Bureau business
☐ Refused by addressee
☐ Refused per la destinatione



CANADA POST
GRANT PARK POSTAL OUTLET
SHOPPING CENTRE
WILKINSON AVE
WINNIPEG MB R2M 1B0
A50D178



174369155



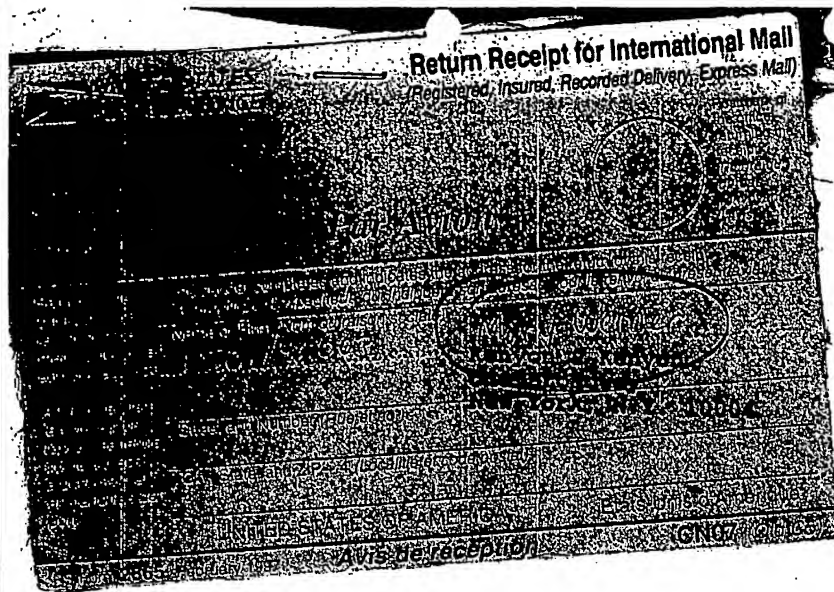
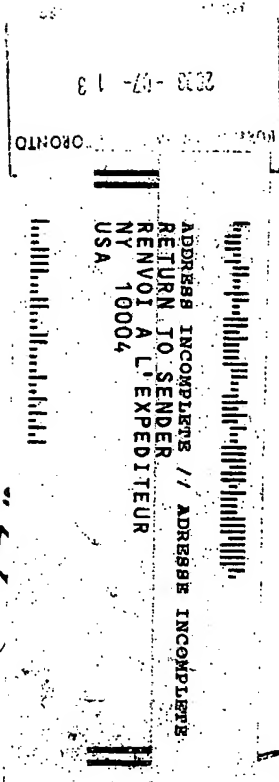


EXHIBIT H



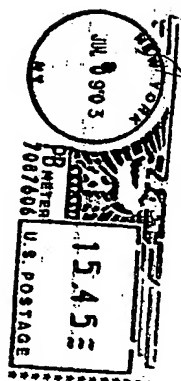
One Broadway
New York, NY 10004-1050

KENYON
Intellectual Property Law

Mr. Robert C. Tuttle
782 Alpegheny Drive
Winnipeg, Manitoba CANADA R3T 5L2

Address incomplete

Post



SOMFAI & PARTNERS

Industrial Rights Co.Ltd.

H-1137 Budapest

Pozsonyi út 38.

Hungary

☐ Special Delivery

☒ Air mail ☒ Registered

☐ Express

☐ Also by fax: - page(s)

Nº: 00 1 212 425 5288

Your letter: 22.06.2004

Copy:

☒ Mr. Silver 1468/01

☒ Mr. Fiedman 1469/01

Tel:(361)3495-298

Fax:(361)3502-623

Law Office Kenyon & Kenyon
One Broadway
NEW YORK N.Y. 10004-1050
U.S.A.
X

Budapest, 08. September 2004

1467/04kj

Mr.
Attention of Patrick J. Birde!

Dear Colleagues,

Re: Continuation Patent Application Nº 10/657737 of
HUMAN RT "Taxalb2" based on US 60/094687
PCT/US99/17179 (originally by Novopharm)
My ref: P-0112 US Please quote!
Your ref: 1662/460041

- 1) Please find enclosed the original *signed*
 - Declaration. 5 pages *
- 2) The signature of Dr. Gábor Pethő is missing. Since we are not able to receive a new one, I suggest to consider my suggestions of my letters dated 19.17.2001 and 28.06.2004.

Sincerely yours


Dr. Eva Somfai

Enclosure: * as above 5 pages

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

DECLARATION

ATTORNEY'S DOCUMENT NO.
11701/46003

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN**, Serial No. 10/293,426, which is a continuation of U.S. Serial 09/947,420 filed September 5, 1991, which is a continuation of 09/744,827, which is the U.S. national phase of International Application PCT/US99/17179, filed July 29, 1999.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

PRIOR UNITED STATES APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER	FILING DATE (day, month, year)
60/094,687	30 July 1998

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this

1 of 5

application:

APPLICATION NUMBER	FILING DATE (day, month, year)	STATUS (i.e. Patented, Pending, Abandoned)
09/744,827	30 January 2001	Abandoned
09/947,420	05 September 2001	Abandoned

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Steven J. Lee, Esq.
KENYON & KENYON
One Broadway
New York, New York 10004-1050

CUSTOMER NUMBER 26646

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR	FAMILY NAME KADIMA	FIRST GIVEN NAME Tenshuk	SECOND GIVEN NAME A.
RESIDENCE & CITIZENSHIP	CITY Winnipeg	STATE OR FOREIGN COUNTRY Manitoba	COUNTRY OF CITIZENSHIP Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS 7 Woodington Bay	CITY Winnipeg	STATE & ZIP CODE/COUNTRY Canada R3P 1M6
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME (Deceased)	FIRST GIVEN NAME	SECOND GIVEN NAME
	KAPLAN	Howard	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	18 Hillhouse Road	Winnipeg	Canada R2V 2V6
Signature (Deceased - See Below)		Date	
Heir and Legal Representative of Howard KAPLAN(Deceased)			
Residence: _____			
Citizenship: _____			
Signature: _____			
Date: _____			
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	TUTTLE	Robert	C.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	782 Allegheny Drive	Winnipeg	Canada R3T 5L2
Signature		Date	

3 of 5

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	HEGEDUS	Lajos	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1121 Eotvos ut 47	Budapest	Hungary
Signature X <i>[Signature]</i>		Date 08/12/2004	
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KREMPELS	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1188 Ady E. ut 204	Budapest	Hungary
Signature <i>[Signature]</i>		Date X 07/15/2004	
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PAAL	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1025 Felsözöldmali ut 80	Budapest	Hungary
Signature X <i>[Signature]</i>		Date 2004 aug. 6.	

4 of 5

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PETHO	Gabor	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1225 Kassai ut 10	Budapest	Hungary
Signature X		Date	

SOMFAI & PARTNERS

Industrial Rights Co. Ltd.
H-1137 Budapest
Hungary

Tel:(361)3495-298

Fax:(361)3502-623

☐ Special Delivery

☒ Air mail ☒ Registered

☐ Express

☒ Also by fax: 2 page(s) + 10

Nº: 00 1 212 425 5288

Your letter: 23/06/2004

Copy for information:

Dr. Livneh 1189/04

Dr. Haber 1186/04

Mr. Silver 1187/04

Dr. Benedek 1190/04

Mr. Friedman 1191/04

Dr. Hegedűs 1192/04

Law Office Kenyon & Kenyon

One Broadway

NEW YORK N.Y. 10004-1050

U.S.A.

X

Budapest, 28. June 2004

F1184, 1185/04s6

Attention of Mr. Patrick J. Birde!

PRIVILEGED AND CONFIDENTIAL!

Dear Mr. Birde, dear Colleagues,

Re: Continuation Patent Application in US N° 10/657737 of
HUMAN RT "TAXALB-2" based on US 60/094687
PCT/US99/17179 (originally by Novopharm)

Your ref: 1662/460041 Mrs. M.C. Werner

My ref. P-0112US-B

Completion of List of Inventors in Cont Appl.

Dear Patrick, I was more than pleased to make your acquaintance at the AIPPI conference in Geneva and I thank you again for inviting me to your company's 125 years celebration reception in the exquisite palace of the ancient "shooters".

I. INVENTORS

1. Thank you for your above fax letter (which arrived here 23/06/2004). You informed me that you had filed a continuation application and you now enclose forms which you ask me to return by fax complete with the Hungarian inventors' signature. You wish to file these in order that you try to accomplish the list of inventors now only comprising inventors Kadima, Kaplan and Tuttle. You request me to send you the signed version before the due date which is the 28th of June (to-day).
2. Please ask for an extension of time to collect the signatures. I have to add that none of the inventors can be found at Human Rt. anymore. In addition: one of the

inventors lives in Canada. Thus to collect all names on one single document is a lengthy program indeed.

3. Please advise by return whether it would be at least adequate to have the inventors sign the document separately (each inventor on a different document). This might speed up the procedure somewhat for those who are ready to sign it.
4. However it is highly dubious whether inventor Pethő will sign the declaration at all. He already refused a similar declaration for other countries stating that he now works for a company who would not allow him to sign anything of the kind.
5. Thus in Canada, Europe and Hungary we used already available documents signed by the inventor's team in relation to the "taxalbin-1" application filed by Human based on the invention of the 4 Hungarian inventors (whose names have to be added in the present matter):

- a) in Canada we filed an
 - Affidavit with enclosed
 - assignments related to the Canadian "taxalbin-1" application dated June 19997 pages *
- b) in Europe we filed a
 - declaration on the basis of the enclosed transfer of rights dated 01/08/1997 and signed before filing of the "Taxalbin-1" Hungarian priority document.4 pages *

The "taxalbin-1" series corresponds to your file 1662/53301 - our files P-9830US-A, B and C". It might be perhaps possible to rely on the signed documents filed in the USA(?) In Europe completion of inventor's names was already officially accepted.

II. CONTINUATION APPLICATIONS

6. You indicated that you had already filed a continuation application. Please let me have the details of said application (filing date and forms). Please also let me have the data of the next new application which you decided to file on 28. June 2004. May I ask the reason why such series of applications is necessary?

Sincerely yours
Dr. Eva Somfai

Enclosure:
11 pages

Best
regards



Re: Canadian Patent Application No. 2,362,338
Applicant: Human Serum & Pharmaceutical
Manufacturing
Title: Pharmaceutically Acceptable
Composition Comprising an Aqueous
Solution of Paclitaxel and Albumin
Filed: July 29, 1999

ENCLOSURE 1

AFFIDAVIT OF DR. EVA SOMFAI

IN THE MATTER OF Canadian Patent Application No. 2,362,338, (the "Present Application") I, Dr. Eva Somfai, in the City of Budapest, Hungary, MAKE OATH AND SAY:

1. I am a Patent Agent with the firm of Somfai & Partners who act on behalf of Human RT, the applicant of the Present Application. As such, I have personal knowledge of the facts stated in this my affidavit.
2. An assignment document, a copy of which is attached as Exhibit "A" to this my affidavit, was recorded in the Canadian Patent Office on August 26, 1999 under Document Registration No. 5048332 for Canadian Patent Application No. 2,269,923 which is based on International Application No. PCT/HU98/00086.
3. The assignment document provided in Exhibit "A" to this my affidavit transfers all right, title and interest of the invention disclosed in Canadian Patent Application No. 2,269,923 from the inventors listed as Krisztina Krempels, Krisztina Paál, Gábor Pethő and Lajos Hegedüs to Human RT, the applicant of both Canadian Patent Application No. 2,269,923 and the Present Application.
4. All of the subject matter disclosed in the specification of the Present Application is also disclosed in Canadian Patent Application 2,269,923.

5. It is respectfully submitted that the assignment document provided in Exhibit "A" to this my affidavit from the inventors of the Present Application listed as Krisztina Krempels, Krisztina Paál, Gábor Pethő and Lajos Hegedűs transferring all rights in and to the invention disclosed in Canadian Patent Application No. 2,269,923 to the applicant Human RT of the Present Application should also be recorded against the Present Application.

SWORN BEFORE ME at the City of
Hungary this day of
2003

)
)
)
)

Dr. Eva Somfai

DR. EVA SOMFAI

A Notary Public and Commissioner



Dr. TÓTH ERZSÉBET KATALIN

Notary

1136 Budapest, Tátra u. 15/a.

Tel/fax: 349-3404, 329-3034

File No: 4256/2003. -----
English language licence No: 35167/1991. IM III. -----
Before me, the undersigned Notary in and for the City of Budapest, personally appeared
Ms. Dr. SOMFAI, Éva, domiciled at Budapest, I. Táncsics M. u. 8. I. 1., Republic of
Hungary, who proved identity by the Hungarian Identity Card No. AH 305918, she
signed this document in my presence. -----
At Budapest on this 2nd (second) day of December, 2003 (two thousand and three). -----

Dr. Tóth Erzsébet Katalin
Dr. TÓTH, Erzsébet Katalin
Notary



This is Exhibit "A" referred to in
the Affidavit of

DR. EVA SOMFAI

Eva Somfai

Sworn before me this day of
, 2003

A Commissioner, etc.



Dr. TÓTH ERZSÉBET KATALIN
Notary
1136 Budapest, Tátra u. 15/a.
Tel/fax: 349-3404, 329-3034

File No: 4256/2003. -----
English language licence No: 35167/1991. IM III. -----
Before me, the undersigned Notary in and for the City of Budapest, personally appeared
Ms. Dr. SOMFAI, Éva, domiciled at Budapest, I. Táncsics M. u. 8. I. 1., Republic of
Hungary, who proved identity by the Hungarian Identity Card No. AH 305918, she
signed this document in my presence. -----
At Budapest on this 2nd (second) day of December, 2003 (two thousand and three). -----



Dr. Tóth Erzsébet Katalin
Dr. TÓTH, Erzsébet Katalin
Notary

CANADA

P-0112CF

Joint Inventors

Assignment

In consideration of One (\$1.00) Dollar, and other good and valuable consideration paid to us by HUMAN Rt. whose full post office address is Tancsics út 82, H-2100 Gödöllő, Hungary, hereinafter called the Assignee, the receipt whereof is hereby acknowledged, we do hereby sell and assign unto the said Assignee, all our right, title and interest in Canada in and to our invention relating to:

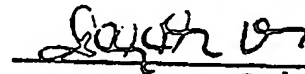
PHARMACEUTICAL COMPOSITIONS CONTAINING PLASMA PROTEIN

as fully described and claimed in the Canadian patent application for such invention based on International Application No. PCT/HU98/00086, and to all our corresponding right, title and interest in and to any patent which may issue therefor.

SIGNED at (1) X

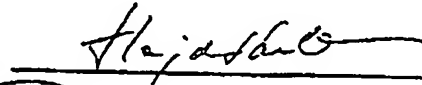
this X 20 day of X June, 1999.

Inventor:



Lajos HEGEDÜS

Witness:



Hajdi L.
Kozlegysz.



Gödö



...2

P-0112CA

SIGNED at (1) X
this X 29 day of X JUNE , 1999.

Inventor: Kempes Krisztina
Krisztina KEMPES X



Witness:

Hajdó

SIGNED at (1) X
this X 29 day of X June , 1999.

Inventor: Pál Krisztina
Krisztina PÁL X



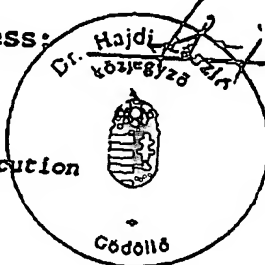
Witness:

Hajdó

SIGNED at (1) X
this X 29 day of X June , 1999.

Inventor: Pál Krisztina
GÁBOR PETHŐ

Witness:



(1) Insert place and date of execution

G. RONALD BELL & ASSOCIATES



Dr. HAJDI LÁSZLÓ
1. sz. KÖZJEGYZŐ
2100 Gödöllő, Remsey krt. 6., Pf. 167.
Tel./Fax: /28/ 430-063, 415-313. Rádiótel.: 06 30 489 426

TANÚSÍTVÁNY

HITELESÍTÉSEK KÖNYVE: 1405., 1406., 1407., 1408/1999. ügyszám:----
Alulírott, dr. Hajdi László gödöllői közjegyző tanúsítom, hogy---
Dr. HEGEDŰS LAJOS (Bp., XII., 1952. 03. 28., an.: Kardos Julian---
na)), Budapest, XI., Oltvány árok u. 16. II/2. (szig.szám: AF851-
367)-----
Dr. KREMPELS KRISZTINA (Bp., VIII., 1967. 07. 09., an.: Hancke Ma-
rianna), Budapest, XVIII., Ady E. u. 204. (szig.szám: AF857343)---
PAÁL KRISZTINA (Bp., XII., 1969. 05. 12., an.: Lipthay Klára),---
Budapest, II. Felsőörmáli u. 80. (szig.szám: AU-VI. 683056)-----
Dr. PETHŐ GÁBOR (Bp., VIII., 1954. 05. 16., an.: Varjas Ferdinan-
da), Budapest, XII., Kassai u. 10. (szig.szám: AU-VI. 596319)-----
szám alatti lakos személyazonossága megfelelő módon való igazolá-
sa után az idefűzött - általam nem beszélt, nem értett - angol---
nyelvű dokumentumot a mai napon előttem saját kezűleg írta alá.---
Kelt Gödöllőn, 1999. Egyezerkilencszázkilencvenkilencedik évi,---
Június hó 29. Huszonkilencedik napján.-----



Hajdi László
Dr. Hajdi László
közjegyző

BEETZ & PARTNER

Patentanwälte
European Patent Attorneys
European Trade Mark Attorneys

BEETZ & PARTNER Steinsdorfstr. 10 D-80538 München

European Patent Office

80298 München

ENCLOSURE 2

P-0112EP
ÉRKEZETT

26-1991) 2001 MARCH 7
-2000)

Dipl.-Ing. J. SIEGFRIED
Prof. Dr.rer.nat. W. SCHMITT-FUMIAN
Dipl.-Phys. Dr.rer.nat. C.-M. MAYR
Dipl.-Ing. A. PFEIFFER
Dipl.-Ing. B. MATIAS

Rechtsanwältin P. KOTSCH

Ihr Zchn.
Your Ref.

Unser Zchn. 64-56.424EP/SF;fk
Our Ref.

München March 16, 2001

European Patent Application 99937616.3 of July 29, 1999
Novopharm Biotech, Inc.

According to our telephone conversation of March 13, 2001, we herewith file the
Designation of Inventor for the additional inventors.

Patentanwälte
BEETZ & PARTNER
Association no. 71

W. SCHMITT-FUMIAN

Encls.

ERFINDERNENNUNG / DESIGNATION OF INVENTOR / DESIGNATION DE L'INVENTEUR

2001 MARCH 21

(falls Anmelder nicht oder nicht allein der Erfinder ist) (where the applicant is not the inventor or is not the sole inventor) / si le demandeur n'est pas l'inventeur ou l'unique inventeur

Zeichen des Anmelders oder Vertreters
Applicant's or representative's reference
Référence du demandeur ou du mandataire
(max. 15 Positionen / max. 15 spaces /
15 caractères au maximum)

64-56.424EP/SF:fk

Nr. der Anmeldung oder, falls noch nicht bekannt, Bezeichnung der Erfindung
Application N° or, if not yet known, title of the invention
N° de la demande ou, si ce dernier n'est pas encore connu, titre de l'invention

99937616.3

In Sachen der obenbezeichneten europäischen Patentanmeldung nennt (nennen) der (die) Unterzeichnete(n) ¹
In respect of the above European patent application I (we), the undersigned ¹
En ce qui concerne la demande de brevet européen susmentionnée le (s) soussigné(s) ¹

BEETZ & PARTNER
Patentanwälte
Steinsdorfstr. 10
D-80538 München

Zusammenschluß Nr. 71

als Erfinder²: *additional*
do hereby designate as inventor(s) ²:
désigne(n) en tant qu'inventeur(s) ²:

- i) DR. HEGEDŰS, Lajos; chemical engineer;
Hungarian citizen;
Eötvös út 47
H-1121, Budapest, Hungary
 - ii) DR. KREMPELS, Krisztina; physician; Hungarian
citizen; Ady E. út 204
H-1188 Budapest, Hungary
 - iii) DR. PAÁL, Krisztina; chemist, Hungarian citizen;
Felsőrédlmáli út 80
H-1025 Budapest, Hungary
 - iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen;
Kassai út 10
H-1225, Budapest, Hungary
- Der (Die) Anmelder hat (haben) das Recht auf das europäische Patent erlangt³
The applicant(s) has (have) acquired the right to the European patent³
Le(s) demandeur(s) a (ont) acquis le droit au brevet européen³



gemäß Vertrag vom
under an agreement dated
par contrat en date du

01.08.1997



als Arbeitgeber
as employer(s)
en qualité d'employeur(s)



durch Erbfolge
as successor(s) in title
par transfert successoral

Ort/Place/Lieu München

Datum/Date March 16, 2001

Unterschrift(en) des (der) Anmelder(s) oder Vertreter(s) /
Signature(s) of applicant(s) or representative(s) /
Signature(s) du (des) demandeur(s) ou du (des) mandataire(s)

W. SCHMITT-FUMIAN

BEETZ & PARTNER
Patentanwälte
Steinsdorfstrasse 10, D-80538 München

Name des (der) Unterzeichneten bitte mit Schreibmaschine wiedergeben. Bei juristischen Personen bitte die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft mit Schreibmaschine angeben! Please type name and signature in case of legal persons, the position of the signer within the company should also be typed! ou les noms des signataires doivent être également dactylographiés. S'il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires sera indiquée à la machine à écrire

Fußnoten befinden sich auf der Rückseite / Footnotes overleaf / Le texte des renvois figure au verso

EPA/EPO/OEB Form 1002 11.98 (int. ad. 1/98)

bitte wenden/ P.T.O. / T.S.V.P.

NYILATKOZAT

DECLARATION

Alulírott feltaláló(k)

The undersigned inventor(s)

Dr. Hegedűs Lajos

Dr. Hegedűs Lajos

Dr. Krämpels Krisztina

Dr. Krämpels Krisztina

Dr. Paál Krisztina

Dr. Paál Krisztina

Dr. Pethő Gábor

Dr. Pethő Gábor

kijelenti(k), hogy

declare(s), that

HUMAN Oltóanyagtermelő és
Gyógyszergyártó Rt.HUMAN Serum Production and
Medicine Manufacturing Co., Ltd

jogosult arra, hogy

is authorized to file in a patent
application for the subject matter of his/her
patent application(s) entitled.

Method for parenteral delivery in therapeutic use of pharmacologically active compounds with
poor solubility in water, and substantial binding to plasma proteins.

című

filed under No(s)

szám(ok) alatt ban

in

benyújtott bejelentés(ek)nek tárgyát
saját nevében szabadalomra

and to claim priority of said patent application.

bejelentse és a fent említett szabadalmi
bejelentés(ek) elsőbbségi jogát igénybe vegye.

Name: Dr. Hegedűs Lajos

Date: 1997.08.01.

Signature(s). *Hegedűs Lajos*

Name: Dr. Krämpels Krisztina

Date: 1997.08.01.

Signature(s). *Krämpels Krisztina*

Name: Dr. Paál Krisztina

Date: 1997.08.01.

Signature(s). *Paál Krisztina*

Name: Dr. Pethő Gábor

Date: 1997.08.01.

Signature(s). *Pethő Gábor*

Name:

Date:

Signature(s)

Name:

Date:

Signature(s)

Name:

Date:

Signature(s)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

DECLARATION

ATTORNEY'S DOCKET NO.
11701/46003

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN**, Serial No. 10/293,426, which is a continuation of U.S. Serial 09/947,420, filed September 5, 1991, which is a continuation of 09/744,827, which is the U.S. national phase of International Application PCT/US99/17179, filed July 29, 1999.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

PRIOR UNITED STATES APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER

FILING DATE
(day, month, year)

60/094,687

30 July 1998

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this

application:

APPLICATION NUMBER	FILING DATE (day, month, year)	STATUS (i.e. Patented, Pending, Abandoned)
09/744,827	30 January 2001	Abandoned
09/947,420	05 September 2001	Abandoned

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Steven J. Lee



26646

PATENT TRADEMARK OFFICE

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KADIMA	Tenshuk	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	7 Woodington Bay	Winnipeg	Canada R3P 1M6
Signature			Date

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KAPLAN	Howard	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	18 Hillhouse Road	Winnipeg	Canada R2V 2V9

Signature

Date

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	TUTTLE	Robert	C.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	782 Allegheny Drive	Winnipeg	Canada R3T 5L2

Signature

Date

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	HEGEDUS	Lajos	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1121 Eotvos ut 47	Budapest	Hungary

Signature

Date

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KREMPELS	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1188 Ady E. ut 204	Budapest	Hungary
Signature	Date		

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PAAL	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1025 Felsőzoldmali ut 80	Budapest	Hungary
Signature	Date		

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PETHO	Gabor	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1225 Kassai ut 10	Budapest	Hungary
Signature	Date		

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

DECLARATION

ATTORNEY'S DOCKET NO.
11701/46003

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN**, Serial No. 10/293,426, which is a continuation of U.S. Serial 09/947,420, filed September 5, 1991, which is a continuation of 09/744,827, which is the U.S. national phase of International Application PCT/US99/17179, filed July 29, 1999.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

PRIOR UNITED STATES APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER

FILING DATE
(day, month, year)

60/094,687

30 July 1998

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this

application:

APPLICATION NUMBER	FILING DATE (day, month, year)	STATUS (i.e. Patented, Pending, Abandoned)
09/744,827	30 January 2001	Abandoned
09/947,420	05 September 2001	Abandoned

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Steven J. Lee



26646

PATENT TRADEMARK OFFICE

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KADIMA	Tenshuk	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	7 Woodington Bay	Winnipeg	Canada R3P 1M6
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KAPLAN	Howard	A.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	18 Hillhouse Road	Winnipeg	Canada R2V 2V9
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	TUTTLE	Robert	C.
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Winnipeg	Manitoba	Canada
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	782 Allegheny Drive	Winnipeg	Canada R3T 5L2
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	HEGEDUS	Lajos	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1121 Eotvos ut 47	Budapest	Hungary
Signature		Date	

FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	KREMPELS	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1188 Ady E. ut 204	Budapest	Hungary
Signature	Date		
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PAAL	Krisztina	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1025 Felsőzoldmali ut 80	Budapest	Hungary
Signature		Date	
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	PETHO	Gabor	
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	Budapest	Hungary	Hungary
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
	H-1225 Kassai ut 10	Budapest	Hungary
Signature		Date	

SOMFAI & PARTNERS
H-1137 Budapest, Pozsonyi út 38
Hungary

tel: (361)3495-298
Fax: (361)3502-623

X Special Delivery
O Air mail O Registered
O Express

X Also by fax: 1 page(s) + 1
Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

Please quote on all
correspondence!

EXHIBIT C

INTERNATIONAL BUREAU OF WIPO
34, chemin des Colombettes
1211 Geneva 20
SWITZERLAND

URGENT!

Budapest, 26. January 2001

F235,236/01s6


Re:	Registration of Assignment of Application		
PCT Application:	PCT/US99/17179 29.07.1999		
PCT Publication:	WO 00/06152	10.02.2000	
Priority:	30.07.1998	US 60/094687	

1. The patent application in caption and all rights related thereto were assigned from the original PCT applicant Novopharm Biotech Inc., 30. Novopharm Court, Toronto, Ontario M1B 2K9, Canada.
2. Data of the present applicant and the signatory:

Assignee: HUMAN Rt. Táncsis út 82. H-2100 Gödöllő, Hungary	Signatory: Lajos HEGEDŰS managing director
---	---
3. Please register the above change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
4. Please find enclosed the
 - Power of attorney signed by the new applicantappointing me to represent this application. 1 page *

Thank you for your co-operation.

Respectfully


Dr. Eva Somfai
patent attorney

Enclosure:

** Fax and Mail: New Power of Attorney
Fax and Mail: Assignment Deed (follows on receipt)

P-0112

1/1

MEGHATA MAZÁS

POWER

Alulírott

The undersigned

HUMAN RT;
Gödöllő, Hungary

HUMAN RT;
Gödöllő, Hungary

ezenel meghatalmazzuk(zom) a
SOMFAI és TÁRSAI
Iparjogi Kft-t

hereby appoint(s)
SOMFAI and PARTNERS
Industrial Rights Co. Ltd.

Szabadalmi ügyvivő:
Dr jur. Somfai Éva
vegyészménők

Patent Attorney:
Dr jur. Eva Somfai
eng. chem.
concerning
Patent and/or Application entitled

hogy az
US 60/094687
PCT/US99/17179
-ra alapított,

Pharmaceutically Acceptable Composition
Comprising an Aqueous Solution of Paclitaxel
and Albumin

Pharmaceutically Acceptable Composition
Comprising an Aqueous Solution of
Paclitaxel and Albumin

című szabadalom és/vagy bejelentés

Nº
based on
US 60/094687
PCT/US99/17179

ügyben az illetékes hatóságok, bíróságok
és hivatalok előtt teljes jogkörrel
képviseljen.

with full power of substitution and
representation before the competent
authorities, courts or offices.

Kelt/Date:

Név (Cég)/ Name (Firm):
HUMAN RT.

Cím/Address:
Táncsics M.u.82.
H-2100 Gödöllő, Hungary

Aláírás(ok)/ Signature(s)::

L. Hegedűs
Managing Director



Name and capacity of signatories

(no legalization is required)

P-0112

SOMFAI & PARTNERS

Industrial Rights Co.Ltd.
H-1137 Budapest
Hungary

11 RT 11701-46001
EXHIBIT D

Tel:(361)3495-298
Fax:(361)3502-623

- X Special Delivery
o Air mail o Registered
o Express
X Also by fax: 3+6 page(s)
Nº: 00 1 212 425 5288
Your letter: -

Law Office Kenyon & Kenyon
One Broadway
NEW YORK N.Y. 10004-1050
U.S.A.
X

URGENT!
IMPORTANT!

Budapest, 26. January 2001

F231, 232/01kj

Attention of Mr. Steven J. Lee! and/or
Mr. Patrick Bird!

PRIVILEGED AND CONFIDENTIAL!

Dear Colleagues,

Re: New Patent Application in US of
HUMAN RT "NOVBIO" based on US 60/094687
PCT/US99/17179
My ref: P-0112 US Please quote!
Your ref: -
NATIONAL APPLICATION TO BE FILED in US

Please

- ☐ File a new patent application in Canada
☒ Enter the national phase of the PCT application in
caption.

To be filed: On/before **30. January 2001**

- ☐ 12 months priority
☐ 20 months PCT
☒ **30 months PCT date.**

If it is possible to file within 31 months in your
country please file timely before the due date.

Documents:	Now enclosed	Follows	Please inform	Remarks
Information sheet	X 2 pages			fax
PCT Publication cover	X 1 page			fax
Specification to be filed	see PCT publ			• 125 pages
Claims to be filed	see PCT publ			• 4 pages

Figures to be filed	see PCT publ			• 28 pages
Abstract	see PCT publ			• 1 page
Power			X	
Inventors decl.			X	
Transfer of rights			X	
Data of newly added inventors	X 1 page			• •
Priority document			X	
PCT Search Report				•
PCT Publication				•
Change of representation and owner filed at WIPO	X 1 page			
Completion of inventor's list filed at WIPO	X 2 pages			
Acceptance by WIPO			X	

- is already in your file (5934/2)
- If you consider it would be better not to file this please
 - ☐ call me before filing any time between 9 and 19 our time
 - ☒ add the names when appropriate.

Please indicate by return fax what else you need. The outstanding documents will follow always with a copy of this letter.

We ask you to send the **filled-in Powers** and all other documents you need in the form **ready for signature**. Empty formulars will not be signed.

- ☒ The priority document was filed in English by the inventors Kadima Tenshuk, Kaplan Howard, Tuttle Robert C.
- ☒ The PCT application was filed by the assignor Novopharm Biotech, CA the prosecution was in English and the application was recently assigned. When writing this order letter the WIPO-registration of both the Assignment and completion of the list of inventors is still pending.

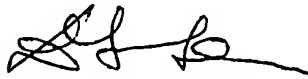
We await your debit notes in duplicate clearly indicating where and how you wish us to settle the same.

Please do not abandon this application if not expressedly instructed to do so.

Please confirm receipt both of the faxed and the mail version of this order letter as well as the documents by fax.

Thanking you for your immediate attention and looking forward to have a good co-operation.

Sincerely yours



Dr. Eva Somfai
chem. ing. patent attorney

Enclosure:

Fax:	6 page(s)
Air mail:	- page(s)
Spec. delivery	6 page(s)

INFORMATION SHEET FOR NEW PATENT APPLICATION

TITLE: Pharmaceutically Acceptable Composition
Comprising an Aqueous Solution of
Paclitaxel and Albumin

APPLICANT: HUMAN RT
Táncsics M.u.82.
H-2100 Gödöllő, Hungary

PRIORITY: 30.07.1998 US 60/094687

PCT APPLICATION: PCT/US99/17179 29.07.1999

PCT PUBLICATION: WO 00/06152 10.02.2000

INVENTOR(S): Kadima, Tenshuk
Kaplan, Howard
Tuttle, Robert C.
Dr. Hegedűs, Lajos
Dr. Krempels, Krisztina
Dr. Paál, Krisztina
Dr. Pethő, Gábor

TO BE
ADDED
WHEN
APPROPRIATE

To be filed: On/before 30. January 2001

☐ 12 months priority

☐ 20 months PCT

☒ 30 months PCT date.

If it is possible to file within 31 months in your
country please file timely before the due date.

ASSIGNMENTS:

☒ The priority application was filed by:
Inventors Kadima, Kaplan, Tuttle (CA)
all of Novopharm Biotech, CA.

☒ The PCT application was filed by:
Novopharm Biotech, CA, except in the US where it
was filed by inventors Kadima, Kaplan, Tuttle.

☒ The application was assigned on HUMAN RT., HU
registration of the change was requested in the
international phase on 26.01.2001

- ☒ The national application has to be filed in the name of HUMAN RT., HU alone.
The assignment documents will follow as soon as available.
- ☒ Because important subject matter of the claimed invention was based on the invention of the four Hungarian inventors now appearing in the list of inventors - registration of completion of the inventor's list was requested on 26.01.2001 at the WIPO.

SOMFAI & PARTNERS
H-1137 Budapest, Pozsony 8
Hungary

Tel: (361)3495-298
(361)3502-623

X Special Delivery
O Air mail O Registered
O Express

EXHIBITE

X Also by fax: 1 page(s)

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

URGENT!

F237,238/01s6

INTERNATIONAL BUREAU OF WIPO
34, chemin des Colombettes
1211 Geneva 20
SWITZERLAND

Budapest, 26. January 2001

Re:	Registration of Change in Person of Inventors
PCT Application:	PCT/US99/17179 29. 07. 1999
Priority:	30. 07. 1998 US 60/094687

1. Reverting to my letter earlier this day I hereby ask to register the following further change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
2. Because important subject matter of the claimed invention was based on the invention of authors whose names did not appear in the list of inventors as originally filed, the Applicant completed the list of inventors by adding of the following persons:
 - i) DR. HEGEDÜS, Lajos; chemical engeneer;
Hungarian citizen;
Eötvös út 47
H-1121, Budapest, Hungary
 - ii) DR. KREMPELS, Krisztina; physician; Hungarian
citizen; Ady E. út 204
H-1188 Budapest, Hungary
 - iii) DR. PAÁL, Krisztina; chemist, Hungarian citizen;
Felsőzöldmáli út 80
H-1025 Budapest, Hungary
 - iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen;
Kassai út 10
H-1225, Budapest, Hungary

Thank you for your co-operation and help.

Respectfully


Dr. Eva Somfai
patent attorney

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**PETITION UNDER 37 C.F.R. §§1.47(b)
and 1.42**

Docket Number:
1662/460041
(formerly 11701/46007)

Application Number
10/657,737

Filing Date
September 3, 2003

Examiner
Not Yet Assigned

Art Unit
1614

Invention Title
**PHARMACEUTICALLY ACCEPTABLE
COMPOSITION COMPRISING AN AQUEOUS
SOLUTION OF PACLITAXEL AND ALBUMIN**

Inventor(s)
KADIMA et al.

Address to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited
with the United States Postal Service with sufficient postage
as first class mail in an envelope addressed to:
Mail Stop Missing Parts, Commissioner for Patents, P.O.
Box 1450, Alexandria, VA 22313-1450 on

Date: 5/18/04 Reg. No. 46,877

Signature: *David K...*

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

The above-identified application is a continuation of U.S. Patent Application Serial No. 10/293,426, filed November 12, 2002, which is a continuation of Serial No. 09/947,420, filed September 5, 2001, which is a continuation of Serial No. 09/744,827 which is a 371 of PCT/US99/17179, filed July 29, 1999, which International Application claims the benefit of provisional application Serial No. 60/094,687, filed July 30, 1998.

The International Application was filed in the name of Novopharm Biotech, Inc. as Applicant for all designated States except the United States (Exhibit A). The inventors, Tenshuk KADIMA, Howard KAPLAN and Robert C. Tuttle, were listed as the applicants for

the United States. See attached copy of first page of published PCT application (Exhibit A).

Novopharm Biotech, Inc. assigned all of its rights in the international and national applications to Human RT in January 2001 (Exhibit B). A change of Applicant was filed with the International Bureau of WIPO on January 26, 2001 along with a Power of Attorney from Human RT appointing Dr. jur. Eva Somfai as Agent for Applicant (Exhibit C).

On January 26, 2001 Dr. Somfai (Human RT's foreign patent counsel) requested Kenyon & Kenyon (Human RT's U. S. patent counsel) to enter the national phase in the United States of PCT/US99/17179. Copies of January 26, 2001 order letter and Information Sheet for New Patent Application are attached (Exhibit D).

On January 26, 2001, Dr. Eva Somfai filed with the International Bureau a Rule 92bis letter requesting the addition of inventors, Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO (Exhibit E).

On April 26, 2001 Kenyon & Kenyon sent a letter to Dr. Somfai sending copies of the application as filed, Declaration and Assignment forms for signing by the inventors three (3) originally-named inventors and a Power of Attorney form for signing by the Assignee, Human RT. Reminder letters were sent to Dr. Somfai on June 29, 2001 and August 30, 2001.

Despite many attempts, Kenyon & Kenyon was unable to contact the three inventors, as did the foreign patent counsel. On July 9, 2003, letters were sent by Kenyon & Kenyon to the three originally-named inventors by Registered Mail, Return Receipt Requested to their last known addresses as follows:

Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan
18 Hillhouse Road
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle
782 Allegheny Drive
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of **Kenyon & Kenyon, No. 11-0600**:

- 1) Basic Filing Fee of \$770.00; ---
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. § 1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of \$1,480.00; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By *Siu K. Lo*
Siu K. Lo
Reg. No. 46,877

KENYON & KENYON
One Broadway
New York, New York 10004
Tel: (212) 425-7200
Fax: (212) 425-5288

CUSTOMER NUMBER 26646

2month

0007350

RTLS

fig u

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

P-0112

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61K 31/337, 47/48, 47/42	A1	(11) International Publication Number: WO 00/06152 (43) International Publication Date: 10 February 2000 (10.02.00)
<p>(21) International Application Number: PCT/US99/17179</p> <p>(22) International Filing Date: 29 July 1999 (29.07.99)</p> <p>(30) Priority Data: 60/094,687 30 July 1998 (30.07.98) US</p> <p>(71) Applicant (for all designated States except US): NOVOPHARM BIOTECH, INC. [CA/CA]; 30 Novopharm Court, Toronto, Ontario M1B 2K9 (CA).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): KADIMA, Tenshuk, A. [CA/CA]; 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6 (CA). KAPLAN, Howard, A. [CA/CA]; 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9 (CA). TUTTLE, Robert, C. [US/CA]; 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 (CA).</p> <p>(74) Agents: WU, Frank et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).</p>	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KO, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	
<p>(54) Title: PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN</p>		
<p>(57) Abstract</p> <p>An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10 % organic solvent and has a pH of about 3.0 to about 4.8, is described. The serum albumin can be fatty or defatted, and the composition can optionally be lyophilized or optionally lyophilized and reconstituted. At least 70 % of the paclitaxel is bound to serum albumin, the ratio of paclitaxel to albumin is at least about 1:5, and the concentration of paclitaxel is at least about 25 µg/ml. Methods of making and using this composition are also provided.</p>		



Patrick J. Birde
Direct 212.908.6452
pbirde@kenyon.com

One Broadway
New York, NY 10004-1050
212.425.7200
Fax 212.425.5288

EXHIBIT F

July 9, 2003

**VIA REGISTERED MAIL -
Return Receipt Requested**

Mr. Tenshuk A. Kadima
7 Woodington Bay
Winnipeg, Manitoba
Canada R3P 1M6

Re: U. S. Patent Application Serial No. 10/293,426
PHARMACEUTICALLY ACCEPTABLE COMPOSITION
COMPRISING AN AQUEOUS SOLUTION OF
PACLITAXEL AND ALBUMIN
Our Ref: 101/701/46003

Dear Mr. Kadima:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,

Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley www.kenyon.com 606995



Patrick J. Birde
Direct 212.908.6452
pbirde@kenyon.com

One Broadway
New York, NY 10004-1050
212.425.7200
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -
Return Receipt Requested**

Mr. Robert C. Tuttle
782 Allegheny Drive
Winnipeg, Manitoba
CANADA R3T 5L2

Re: U. S. Patent Application Serial No. 10/293,426
PHARMACEUTICALLY ACCEPTABLE COMPOSITION
COMPRISING AN AQUEOUS SOLUTION OF
PACLITAXEL AND ALBUMIN
Our Ref: 11701/46003

Dear Mr. Tuttle:

We are contacting you on behalf of our client, Human RT.

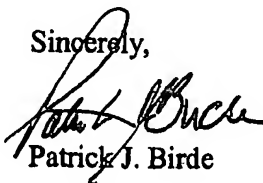
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this mater.

Sincerely,



Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley www.kenyon.com 608453



Patrick J. Birde
Direct 212.908.6452
pbirde@kenyon.com

One Broadway
New York, NY 10004-1050
212.425.7200
Fax 212.425.5288

July 9, 2003

**VIA REGISTERED MAIL -
Return Receipt Requested**

Mr. Howard A. Kaplan
18 Hillhouse Road
Winnipeg, Manitoba
CANADA R2V 2V9

Re: U. S. Patent Application Serial No. 10/293,426
PHARMACEUTICALLY ACCEPTABLE COMPOSITION
COMPRISING AN AQUEOUS SOLUTION OF
PACLITAXEL AND ALBUMIN
Our Ref: 11701/ 46003

Dear Mr. Kaplan:

We are contacting you on behalf of our client, Human RT.

As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this mater.

Sincerely,



Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)
Steven J. Lee, Esq. (w/o enc.)

New York Washington, DC Silicon Valley www.kenyon.com 608451

EXHIBIT B

ASSIGNMENT

We, the undersigned Assignor

Novopharm Biotech Inc.
30, Novopharm Court
Toronto, Ontario, M1B 2K9 Canada

declare to have assigned our exclusive rights related to
patent applications/patents indicated below on

XXXXXX RE.
Tenesio M.u.02.
M-2100 Gedölls, Hungary

We also agree that this assignment be entered in the
register of all international or national patent
authorities.

Data of the patent application:

Number: PCT/US09/17179
Title: "Pharmaceutically Acceptable Composition
Containing an Aqueous Solution of Paclitaxel
and Albumin"
Priority: US 60/004607 30. July 1998

For the Assignor:

Date:
Toronto, January 2001

For the Assignee:

Date:
Gedölls, January 2001

Signed by:



Capacity: MICHAEL A. BYRNE
CHIEF FINANCIAL OFFICER

Signed by:

Lajos Hegedus

Capacity: General manager

P-0:12

HUMAN
SERUM PRODUCTION AND
MEDICINE MANUFACTURING
COMPANY LIMITED BY SHARES
Tenesio M. u. 02.
Gedölls, Hungary
2100

Werner, Mary

EXHIBIT I

From: Werner, Mary
Sent: Friday, August 01, 2003 2:03 PM
To: Butler, Timothy
Subject: RE: 11701/46001 - for Tuesday

Thanks, Tim.

-----Original Message-----

From: Butler, Timothy
Sent: Friday, August 01, 2003 2:01 PM
To: Werner, Mary
Subject: RE: 11701/46001 - for Tuesday

Mary

It turns out that they can only obtain this information for people in the US. I'm going to hold on to this and try Westlaw next week. This was the answer which I received from your Lexis representative.

-----Original Message-----

From: Werner, Mary
Sent: Thursday, July 24, 2003 6:36 PM
To: Butler, Timothy
Subject: 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

Werner, Mary

From: Butler, Timothy
Sent: Wednesday, August 06, 2003 7:22 PM
To: Werner, Mary
Subject: RE: 11701/46001 - for Tuesday

Mary
I tried again with West law . sorry no results

-----Original Message-----

From: Werner, Mary
Sent: Thursday, July 24, 2003 6:36 PM
To: Butler, Timothy
Subject: 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

PITBLADO
ARRISTERS & SOLICITORS

EXHIBIT J

2500 - 360 Main Street
Winnipeg, Manitoba
Canada R3C 4H6

Tel. (204) 956 0560
Fax (204) 957 0227
E-mail firm@pitblado.com

Reply to:
Robert A. Watchman
Direct (204) 956 3568
watchman@pitblado.com

File No. 34052/1

VIA TELECOPIER 212-425-5288

March 22, 2004

Kenyon & Kenyon
One Broadway
New York, NY 10004-1050

Attention: Slu K. Lo

Dear Sir:

Re: U.S. Patent Application Serial No. 10/293,426
Your Reference: 1662/46003

This will acknowledge receipt of your letter dated March 11, 2004 enclosing documentation with respect to the above-noted application.

As you may recall in our telephone conversation of September 3, 2003, because of the particular wording of the inventor's declaration for the United States, the representative of Dr. Kaplan's estate cannot sign the declaration. That is, the wording requires her to declare, under threat of penalty, that she has reviewed and understands the content of the specification, including the claims, amongst other things.

We wish to emphasize that Ms. Grad does not wish to appear to be uncooperative and she is not disputing the application or your client's entitlement to the invention, it is simply that she cannot sign the declaration as worded.

In our telephone discussion, I referred to other patent applications in which the same issue arose in which the applicant proceeded on the basis that the representative "refuses" to sign the declaration, which I believe is provided for in 37 CFR 1.42.

In our September 3, 2003 telephone conversation, you indicated that you believe the rules might have provided for some variation when the documents were to be signed by a representative. However, unless there is some other wording for the declaration, the representative of Dr. Kaplan's estate will not be able to sign.

Yours very truly,

PITBLADO

per: *Robert A. Watchman*
Robert A. Watchman
RAW:dew